

### **Remarks**

Applicants have carefully considered this Application in connection with the Examiner's Action, and respectfully requests reconsideration of this Application in view of the foregoing amendments, and the following remarks.

Claims 1 – 28 remain pending in the present application. The amendments are made based upon support in Applicants' specification and comply with the proposals made by the Examiner. Claims 29-30 are cancelled from the present application, without prejudice to Applicants' ability to later prosecute this subject matter claimed therein in a subsequently filed Continuation application.

No new matter is added.

#### **Response to the Rejection under 35 U.S.C. §101**

The Examiner has rejected claims 25-29 and 30 under 35 U.S.C. §101 as being directed to non-statutory subject matter. However, in light of the Examiner's comments, claim 25 and claims 26-28 dependent thereon have been amended so that the computer readable medium is expressly defined as a "computer readable, non-signal bearing medium" as suggested by the Examiner. Thus, the rejection is, therefore moot, and Applicants ask that it be withdrawn.

Claim 29 is cancelled from the present application as indicated above.

In addition, the Examiner has identified claim 30 as rejected, but has made no indication in the Office Action of why claim 30 is rejected under §101. Accordingly, Applicants have assumed that the inclusion of claim 30 in this rejection is an oversight, remaining from the text of the previous rejection, and it was not intended in the present rejection. Nevertheless, claims 30 is cancelled from the present application as indicated above, and any rejection is moot.

#### **Response to the Rejection under 35 U.S.C. §112, first paragraph.**

The Examiner has rejected claims 1, 17 and 19 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement and introducing new matter. However, Applicants respectfully disagree. The meaning of the cited claim language "compiling a report or revised image based upon the FDT calculation" is disclosed in the specification and is not new matter. Nevertheless, to advance the prosecution, Applicants have amended the claims to read "compiling a plot or revised image based upon the computed FDT."

The specification teaches an input image and an output image. A FDT of 0.0 refers to the input image. Upon calculations based on the FDT algorithm, an output image is created. Specifically, see step 12 which expressly teaches “output the FDT imaged.” Applicants have previously used the term “calculated” with reference to the FDT. However, the Examiner appears to be rejecting the use of the term because the exact word is not found in the specification. Yet, certainly there can be no indefiniteness regarding the meaning of the term “calculating,” nor is it new matter with regard to Applicants’ specification, which fully describes and applies a mathematical principle that allows images at low resolution to be transformed into a plot or a report or a revised image that provides structural thickness of objects, rather than blurry, low resolution images.

It is well accepted in patent law that claims define the invention, and that the description must convey with reasonable clarity that inventor had actually invented what is claimed. The MPEP 2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, “Written Description” Requirement states that “If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, *e.g.*, *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “the description need not be in *ipsis verbis* [*i.e.*, “in the same words”] to be sufficient”).

Thus “specific disclosure in the specification,” as required by the Examiner for each and every word used in the claims - is not the proper US patent standard. *Ipsis verbis* is not required so long as the meaning is clear. Applicants’ use of the terms “calculating” and “report” would be clearly understood by one of ordinary skill in the art of using algorithms or mathematics to produce a useful output, when equivalent words and description is provided in the specification – which Applicants argue is provided in their present specification. Thus, the burden shifts to the Examiner to show why such an individual would not find the meaning of Applicants’ claim language to be to sufficient when “equivalent,” known and understood terms are used in the claim, as opposed to requiring “identical” words from the specification, and why such words would introduce new matter.

Nevertheless, since the terms are equivalent, but without acknowledging that “calculating” or “report” were in any way indefinite, Applicants point out that the phrase

“computed FDT” is specifically supported in Applicants’ specification at paragraphs [0016], [0025], [0027], [0142], and throughout the specification. The algorithm terminates in a finite number of steps and when it does, it outputs the FDT image or a plot. The term “plot” is supported in Applicants’ figures, and for example, paragraphs [0030], [0032], [0038], etc. Thus, the cited claim language is neither new matter, nor indefinite, because the identical words are disclosed in the specification.

The rejection is, therefore moot, and Applicants ask that it be withdrawn.

Response to the Rejection under 35 U.S.C. §102(a).

The Examiner has rejected claims 1, 17, 25, 29 and 30 under 35 U.S.C. §102(a) as anticipated by newly cited Takahashi *et al.*, *Proc. Intl. Soc. Mag. Reson. Med.* 10 (May 18-24, 2002). However, Applicants reply that the subject matter of the Takahashi and paper would be expected to contain elements of Applicants’ claimed invention since three of the authors (See authors: Saha, Wehrli, Gomberg & Takahashi) of the cited paper, are named inventors (Saha, Wehrli and Gomberg) of the present invention, and the paper discloses certain elements of the invention that they were reporting in 2002.

Section 102(a) states that “A person shall be entitled to a patent unless - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. The case law and MPEP 706.02(a) state that “an Applicant’s own work, even though publicly disclosed prior to his application, may not be used against him as a reference, absent the existence of a time bar to his application.” *In re DeBaun*, 214 USPQ 933, 935 (C.C.P.A. 1982). The time bar referred to is the 1-year time bar set forth in 35 U.S.C. §102(b) (the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States).

Consequently, the case law states that:

One’s own work is not prior art under §102(a), even though it has been disclosed to the public in a manner or form which otherwise would fall under §102(a). Disclosure to the public of one’s own work constitutes a bar to the grant of a patent claiming the subject matter so disclosed (or subject matter obvious therefrom) only when the disclosure occurred more than one year prior to the date of the application, that is, when the disclosure creates a one year time bar under §102(b). *In re Katz*, 215 USPQ 14, 17 (C.C.P.A. 1982).

Dr. Wehrli's attached Declaration under 37 C.F.R. 1.131 shows that Applicants' invention preceded the report of certain elements of their invention in the cited Takahashi paper, meaning that the invention could not have been anticipated by the cited paper for the purposes of 102(a). Of course, the cited paper is limited in what is actually disclosed, and as a result it does not anticipate Applicants' invention under the requirements of §102. The Takahashi paper fails to teach each and every element of the claim – failing to describe how to assign to a point in the fuzzy subset its respective fuzzy distance from a complement of a support of the fuzzy subset.

While Dr. Takahashi was named as an author on the cited paper, he was not an inventor, which would have required his contribution to the conception of the claimed invention. Dr. Takahashi was a postdoctoral fellow in the Wehrli laboratory at the University of Pennsylvania, working under the direction and supervision of Dr. Wehrli. Dr. Takahashi was included as an author on the cited paper only because Drs. Saha, Wehrli and Gomberg were using the presently claimed fuzzy distance transform-based computational method for analyzing digital images defining a volumetric region of an object from an image to reexamine data from work that Dr. Takahashi had previously reported. (See reference 5 of cited Takahashi paper). The previously reported work in Dr. Takahashi's ISMRM paper did not use the presently claimed methods. His previously reported "data" was reexamined by the inventors to test and confirm the effect of using the presently claimed method, but Dr. Takahashi was not part of Applicants' present invention and offered no contribution to its conception. Dr. Takahashi did not operate in the laboratory without the supervision of one or more of the inventors.

Regarding Attribution, the MPEP 716.10 states that:

Where there is a published article identifying the authorship ( MPEP § 715.01(c)) or a patent or an application publication identifying the inventorship ( MPEP § 715.01(a)) that discloses subject matter being claimed in an application undergoing examination, the designation of authorship or inventorship does not raise a presumption of inventorship with respect to the subject matter disclosed in the article or with respect to the subject matter disclosed but not claimed in the patent or published application so as to justify a rejection under 35 U.S.C. 102(f).

However, further recognizing that it is incumbent upon the inventors named in the application to provide a satisfactory showing by way of affidavit that the inventorship of the application is correct in that the reference discloses subject matter derived from the Applicant - rather than invented by the author, patentee, or applicant of the published application notwithstanding the authorship of the article or the inventorship of the patent or published

application – in the attached Declaration, Dr. Wehrli has further clarified any ambiguity regarding Dr. Takahashi's authorship. Because there is no evidence to the contrary, Dr. Wehrli's uncontradicted "unequivocal statement," although in a 131 Declaration, rather than in a separate 132 Declaration, regarding the subject matter disclosed in the cited paper should be accepted as establishing inventorship.

Accordingly, the cited "Fuzzy distance transform" paper is not an appropriate prior art reference under 102(a) against Applicants' invention. Applicants respectfully ask that the rejection under 35 U.S.C. §102(a) be reconsidered and withdrawn.

Response to the Rejection under 35 U.S.C. §103(a).

The Examiner has rejected claims 2-16, 18-21 and 26-28 under 35 U.S.C. §103(a) as obvious over Takahashi *et al.*, (*Proc. Intl. Soc. Mag. Reson. Med.* 10 (May 18-24, 2002), in view of Wang (*IEEE*, 1992, pages 114-1192). In making this rejection the Examiner states that Wang fills the gaps left by Takahashi with regard to Applicants' invention by disclosing "assigning to a point in the fuzzy subset its respective fuzzy distance from a complement of a support of the fuzzy subset."

Applicants' traverse the Examiner's conclusion first because as explained in Dr. Wehrli's Declaration under 1.131 and above, the cited Takahashi paper is not a proper basis for a §103 obviousness rejection ["A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title."] Secondly, even if the Takahashi reference did qualify as prior art under either §102(a) or 103 (which it does not), Wang teaches "binary" imaging – not the use of a fuzzy distance transform. Thus, even in combination, the two cited references fail to teach each and every element of Applicants' claimed invention.

Wang's Abstract begins by stating that "A generalized distance transformation (GDT) of *binary images* and the related medial axis transformation (MDT) are discussed." Yet nowhere in the cited Wang paper is fuzzy distance transformation discussed or applied.

Applicants' claimed invention is specific to a "fuzzy distance transform-based computational method for analyzing digital images defining a volumetric region of an object from an image." This is neither taught nor suggested by a discussion of binary imaging. Applicants' have described the advantages of using a fuzzy distance transform over binary imaging in the Background of the Invention section of their specification. The distance between two points is the Euclidian length (See specification at paragraph [0069] "Although only hard

adjacency relations are considered to define a path, the Euclidean distance between two adjacent points should be used in a meaningful way in defining its length”). Using fuzzy distance transforms, a straight line is no longer considered to be the shortest distance between two points, which contradicts the old theories upon which support binary imaging, such as taught by Wang.

For example, at paragraph [0080] of the specification, Applicants’ explain why binary imaging is inappropriate for the methods of the presently claimed invention:

A basic reason behind this is the fact that in a binary image the shortest path from a point to the background (the complement of the binary object) is always a straight-line segment (in a digital sense). However, this is not true for fuzzy digital object (see FIG. 8). This makes a raster scan based approach inappropriate in computing FDT, as illustrated by example in FIG. 8.

Binary imaging is very limited in that it uses only 0 (background) and 1 (object), offering no possible way to account for the gradations in between. For that reason, fuzzy distance logic was developed and applied to the problems overcome in Applicants’ claimed invention. Fuzzy distance accounts for all points. Consequently, the shortest path between 2 points may actually be convoluted, meaning that the length is fuzzy.

Therefore, Takahashi is not a proper prior art reference, and Wang cannot stand alone as a basis for finding Applicants’ invention obvious. Even if Takahashi were a proper reference, the Examiner has pointed to deficiencies in the cited reference that would require the addition of Wang, yet for the reasons shown, Wang fails to teach or utilize fuzzy distance logic. Wang teaches only binary imaging, which defines an entirely different principle than the fuzzy distance transforms used in Applicants’ invention, which utilizes the calculation and production of much sharper images than were previously possible in the prior art.

Together, the cited references fail to provide a proper basis for a §103 rejection. Accordingly, Applicants respectfully ask that the rejection under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Response to the Second Rejection under 35 U.S.C. §103(a).

The Examiner has rejected claims 22-24 under 35 U.S.C. §103(a) as obvious over Takahashi *et al.* (*Proc. Intl. Soc. Mag. Reson. Med.* 10 (May 18-24, 2002), in view of the Gomberg 2002 Doctoral Dissertation (“In vivo magnetic resonance based virtual bone biopsy”) of record. In making this rejection the Examiner states that Gomberg fills the gap left by

Takahashi with regard to Applicants' invention by disclosing suggesting a therapy based on diagnosis or evaluation.

Applicants' traverse the Examiner's conclusion, first because as explained Takahashi is not a proper prior art reference. See, Dr. Wehrli's Declaration under 1.131. Secondly, even if the Takahashi reference did qualify as prior art under either §102(a) or 103 (which it does not), the Gomberg thesis is not a proper prior art reference since Dr. Gomberg is a named inventor on the subject application. Applicants' attach hereto a Declaration by Dr. Gomberg under 1.131 stating that that Applicants' invention preceded the publication of his thesis that reports certain elements of their invention, meaning that the invention could not have been anticipated by the cited paper for the purposes of 102(a). See arguments regarding 102(a) rejection which are applied to the Gomberg Declaration as well.

Although Applicants do not concede that the Gomberg thesis teaches each and every element of the claims 22-24, the cited thesis is not an appropriate prior art reference under 102(a) against Applicants' invention. Applicants respectfully ask that the rejection under 35 U.S.C. §102(a) be reconsidered and withdrawn.

Applicants respectfully assert that in light of the amendments to the claims and the correction of inventorship, this point of rejection is now moot. As discussed above, the cited paper "Fuzzy distance transform: Theory, algorithms and applications" is Applicants' own work, and as such is inappropriate as a prior art reference.


As a result, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

In conclusion, Applicants assert that all pending claims are in condition for allowance. Consequently, Applicants respectfully requests that allowance be granted at the earliest date possible. Should the Examiner have any questions or comments regarding Applicants'

Response, the Examiner is asked to contact Applicants' undersigned representative at (215) 772-7550.

Respectfully submitted,

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Encl:

- (1) Declaration of Felix W. Wehrli under 37 C.F.R. §1.131
- (2) Declaration of Bryon Gomberg under 37 C.F.R. §1.131